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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,611	11/21/2001	Lorraine Faxon Meisner	121753-1005	4194

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Winstead Sechrest & Minick PC
P O Box 50748
1201 Main Street
Dallas, TX 75250-0784

EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/990,611	Applicant(s) MEISNER, LORRAINE FAXON	
	Examiner Frank I. Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-12,15-18,21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-12,15-18,21 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Amended Appeal Brief, filed on 1/5/2006, PROSECUTION IS HEREBY REOPENED. The grounds for rejection are set forth below.

To avoid abandonment of the application, Applicant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then Applicant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-8, 10-12,15-18,21,23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitzky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591) and Bassford et al. (US Pat. 2,517,276).

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Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2). A formulation is disclosed in Table 1 containing among other ingredients, water (58.85 %), glycerine, propylene glycol, zinc sulfate (2.08 %), ascorbic acid (10.06%) and tyrosine and a control formulation is disclosed which contains the same ingredients as set forth in Table 1 except that it does not contain tyrosine or ascorbic acid (Column 3, lines 8-46, Column 4, lines 1-27).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught

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that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein discloses disclosed that ascorbic acid's activity as anti-oxidant has beneficial pharmaceutical effects with regards to adverse changes in the skin brought about by environmental conditions such as UV exposure but that ascorbic acid is unstable (Column 1, lines 12-68, Column 2, lines 1 –7). It is disclosed that invention in Herstein relates to stable topical cosmetic/ pharmaceutical emulsion compositions containing ascorbic acid and that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 1, lines 5-11, Column 2, lines 40-47, Column 10, lines 6-17).

Bassford et al. disclose methods of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60 degrees Celsius, for example 105 g in 140 cc, 100 g in 140 cc, 30 g in 30 cc (Column 4, lines 16-33, Column 5, lines 60-76, Columns 6-8). It is disclosed that when preparing pharmaceutical compounds it is generally advisable to effect the final purification by crystallizing a first crop of pure material in the conventional manner that is disclosed as being Experiment B (Column 3, lines 30-35, Column 5, lines 60-68, Column 6, lines 39-76, Column 7).

The prior art discloses topical compositions containing ascorbic acid, zinc sulfate and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 5% of ascorbic acid, non-toxic zinc salt, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and zinc, the use of ascorbic acid up to 20% and that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin. Further, the prior art

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discloses the preparation of pure ascorbic acid for pharmaceutical use in which one of the steps includes dissolving ascorbic acid in water at 60 degrees Celsius. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,3-8, 10-12,15-18,21,23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitzky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043) and Bassford et al. (US Pat. 2,517,276).

Schinitzky et al. is cited for the same reasons as above and incorporated herein to avoid repetition.

Murad is cited for the same reasons as above and incorporated herein to avoid repetition.

Darr et al. disclose that ascorbic acid's activity as anti-oxidant has beneficial pharmaceutical effects with regards to adverse changes in the skin brought about by environmental conditions such as UV exposure but that ascorbic acid is unstable (Column 1, Column 2, lines 1 –55). It is disclosed that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form and facilitates entry of

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ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). It is disclosed that at even at a pH of 4.5, a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27). It is disclosed that carriers for topical application useful in practicing the invention include but are not limited to alkylene glycols, such as propylene glycol, or alkylene glycols in combination with hydroxyalkylcellulose derivatives, such as hydroxypropylcellulose, and glycerol (Column 3, lines 33-53). It is disclosed that ascorbic acid can be present in amounts of at least about 1 wt. %, preferably from about 3 to 20 wt.%, and more preferably about 5 to 10 wt.% in water and a carrier for topical application (Column 3, lines 18-33).

Bassford et al. is cited for the same reasons as above and is incorporated herein to avoid repetition.

The prior art discloses topical compositions containing ascorbic acid, zinc sulfate and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 5% of ascorbic acid, non-toxic zinc salt, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and zinc, the use of ascorbic acid up to 20% and a pH of about 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a solution of ascorbic acid at a pH of about 3.5 would be stable and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the

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art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Response to Arguments

The rejection of claims 1,3-8, 10-12, 15-18, 21, 23-25 under 35 U.S.C. 103(a) as being unpatentable over Schinitzky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591) and Bassford et al. (US Pat. 2,517,276) is proper.

Applicant acknowledges that Schinitzky et al. teaches the combination of tyrosine (an amino acid), ascorbic acid and a non-toxic zinc salt (Amended Appeal Brief (1/5/2006), page 10). Applicant then argues that Schinitzky et al. do not teach or suggest the use of zinc salt alone or in combination with ascorbic acid without tyrosine. However, contrary to Applicant's arguments, only zinc sulfate, not tyrosine, was identified as an essential ingredient in Schinitzky et al. (Schinitzky et al., Column 2, lines 54-68, Column 3, lines 1-7). The preliminary trial tested against a control containing no ascorbic acid and no tyrosine, however, there is no indication as to the level of effectiveness of the control cream. The results of the preliminary trial only supports a conclusion that the combination of ascorbic acid, zinc sulfate and tyrosine was effective in reducing wrinkles. Schinitzky et al. does not provide any evidence that there was no improvement with wrinkles with the control formulation or that tyrosine is an essential ingredient as the control formulation did not include both ascorbic acid and tyrosine, i.e. there was not control formulation in which only tyrosine was missing, and the results of the control

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formulation were not provided. In any case, the claims do not exclude the use of tyrosine. In fact, claims 21 and 23 require the inclusion of compounds defined only by functional language which the Specification indicates includes "a tyrosine compound" which is defined to be tyrosine or a compound capable of generating tyrosine (Specification, Page 5, lines 10, 11, Page 8, lines 9-17).

Herstein discloses a two-component system, however, the two-component system is only for purposes of storage stability and the final composition is a stable emulsion (Herstein, Column 3, line 1-6, Column 10, lines 6-44). Further, the organoclay is used to stabilize the emulsion not to provide a pH 3.5 to 4.1 in the final composition as this is provided by the use of pH adjusting or buffering compounds (Herstein, Column 10, lines 16-23). Applicants reference to one of the background art cited by Herstein does not provide any evidence that Herstein is solely directed to the use of a new stabilizer and not the combination of ascorbic acid, water and zinc salt. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 158 USPQ 275, 277 (CCPA 1968)).

Applicant argues that there is no motivation or suggestion provided by Schinitzky et al. or Herstein to combine the teaching of the other to arrive at the claimed topical composition. However, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071,

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5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). In this case, Herstein discloses adjusting the pH of a topical cosmetic/ pharmaceutical emulsion containing ascorbic acid to a pH within 3.5 to 4.1. Herstein further discloses that said pH range facilitates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule. As such, one of ordinary skill in the art would have been motivated to modify the prior art composition disclosed or suggested in Schinitzky et al. to have a pH range of 3.5-4.1 with the expectation that pH range would facilitate entry of ascorbic acid, which is disclosed to have beneficial effects against adverse skin conditions, into the skin and/or stabilize the ascorbic acid molecule, which is disclosed to be unstable.

Applicant argues that in Murad ascorbic acid must be used in combination with amino acids and sugar, however, Applicant's claims do not exclude the use of amino acids or sugars. In fact, the compounds listed in claim 6 are amino acids and the compounds listed in claims 7, 8 are sugars, i.e. aminosugars. Applicant cites to various preferred examples or embodiments, however, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971). Applicant argues that Murad does not teach or suggest a two-component system or unique stabilizer. However, the mere fact that one reference discloses elements not disclosed in another

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reference does not overcome the rejection herein. See e.g. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) (The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art). Contrary to Applicant's arguments, Murad, as indicated above, does disclose or suggest topical compositions containing ascorbic acid, zinc salt and water. Further, the rejection herein is based on combination of references, as such, Murad does not have to teach or suggest each and every element of the claimed composition. Finally, as indicated above, there need not be an express motivation to combine the references disclosed in the prior art. In any case, Murad, as indicated above, discloses the benefits of zinc, ascorbic acid, sugars and amino acids, as such, one of ordinary skill in the art would have been motivated to combine the same with the expectation that the combination would exhibit the disclosed benefits.

As indicated above, there is no requirement that Bassford et al. provide an express motivation to combine its teachings with that of the other prior art or set forth each and every element of the claimed composition. As indicated above, Bassford et al. discloses a process for purifying ascorbic acid in which one of the disclosed or suggested uses of the ascorbic acid is as a pharmaceutical compound. As such, one of ordinary skill in the art would have been motivated to use the process disclosed in Bassford et al. with the expectation that the ascorbic acid, thus treated, would be sufficiently pure for use as a pharmaceutical in the prior art pharmaceutical compositions. The reason or motivation to modify the reference may often suggest what the

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inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). The Applicant does not indicate that the limitation "pre-treated ascorbic acid" is limited to any one process of pre-treatment. Applicant has argued in the withdrawn enablement rejection that alternative methods of ascorbic acid pretreatment are known to those skilled in the art (Amended Appeal Brief (1/5/2006), Page 6). However, the only method explicitly disclosed in the Specification includes dissolving ascorbic in water and heating to 60 to 90 degrees Celsius (Specification, page 4, lines 29-32, page 5, lines 1-2). In any case, since Applicant does not specifically indicate that pre-treatment is limited to any one process, the process in Bassford et al. falls within the scope of the limitation "pre-treated ascorbic acid".

The rejection of Claims 1,3-8, 10-12, 15-18, 21, 23-25 under 35 U.S.C. 103(a) as being unpatentable over Schinitzky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043) and Bassford et al. (US Pat. 2,517,276) is proper.

The examiner acknowledges that the claims require at least 5% w/v ascorbic acid, non-toxic zinc salt and water, and a pH of 3.5-4.1, however, this does change the fact that the claims are obvious over the prior art. The only difference between the rejection above and the rejection herein is the use of Darr et al. instead of Herstein. As such, the combined teachings of the prior art without Darr et al. disclose or suggest all the elements of the claimed invention except for a pH falling within the range of 3.5-4.1. In fact, Schinitzky et al., as indicated above, by itself discloses a composition containing water, over 5% ascorbic acid and zinc sulfate. Further,

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Schinitsky et al., with specific reference to the teaching of the combination of ascorbic acid and zinc sulfate, was first applied to reject the claims herein in combination with Darr et al. and Murad in a Non-Final Office Action (See Office Action (10/4/2004), pages 7, 8). The Bassford et al. reference herein replaces the Taylor reference used in said Office Action. Applicant in response to said Office Action did not argue that Schinitsky et al. does not disclose the combination an amount of ascorbic acid which falls within the range of least 5% by weight and a non-toxic zinc salt (Remarks (1/6/2005), pages 8, 9). Further, Applicant does not now argue that Schinitsky et al. does not disclose said combination of ascorbic acid and non-toxic zinc salt. Since Applicant filed an Appeal Brief without otherwise responding to the Non-Final Office Action dated 5/9/2005, the Examiner had no opportunity to correct prior to being apprised of the inadvertent use of "aminosugar" instead of "non-toxic zinc salt" in the rejection herein. As such, in light of above, the same should not be sufficient establish that the claims are not prima facie obvious over the combined teachings of the prior art.

As indicated above, there is no requirement in a rejection based on a combination of references that each reference alone disclose each and every element of the claimed invention. As such, the mere fact that Darr et al. does not disclose the use of a zinc salt or pre-treatment of ascorbic acid does not overcome the rejection herein. Contrary to Applicant's arguments, Darr et al. does not teach away from high quantities of ascorbic acid and pH above 3.5. Applicant acknowledges that Darr et al. discloses a pH of no more than about 3.5. The claimed invention has a minimum pH of 3.5. Therefore, Darr discloses a pH falling within the scope of Applicant's claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 191 USPQ 90 (CCPA 1976); In re

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Woodruff, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); In re Geisler, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms].") The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range.").

Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.).

Applicant's description of the data in Darr et al. is misplaced as Darr et al. discloses that the data in Figures 3, 4 and 5 show that a 5% concentration of ascorbic acid even at relatively high pH's was stable (Darr et al., Column 5, lines 1-27). Further, as indicated above, Darr et al. discloses concentrations of ascorbic acid as high as 20%. Thus, the data in Darr et al. cited by Applicant is not sufficient to establish that Darr et al. does not suggest high concentrations of ascorbic acid and pH's greater than 3.5.

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Applicant argues that there is no teaching or suggestion the prior art references to combine the teachings of Darr et al. with the compounds found in Schinitzky et al. and Murad and the purification of ascorbic acid of Bassford et al.. As indicated above, there is no requirement that the prior art disclose an express motivation in the art to combine the references. Darr et al., as indicated above, discloses that a pH of not more than about 3.5 facilitates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule. As such, one of ordinary skill in the art would have been motivated to modify the prior art composition to have a pH of not more than about 3.5 with the expectation that a pH of about 3.5 would facilitate entry of ascorbic acid, which is disclosed to have beneficial effects against adverse skin conditions, into the skin and/or stabilize the ascorbic acid molecule, which is disclosed to be unstable. Finally, there is motivation to modify and/or combine the teachings of Schinitzky et al., Murad and Bassford et al. as indicated above. As such, there is motivation to modify and/or combine Schinitzky et al., Murad, Darr et al. and Bassford et al.

Conclusion

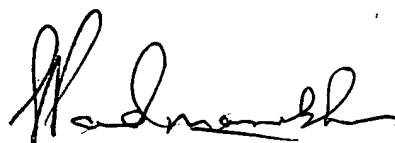
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
September 5, 2006



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER